UNITED NATIONS

A E

General Assembly

Economic and Social Council

Distr.
GENERAL

A/47/222
E/1992/57
8 June 1992

ORIGINAL: ENGLISH

GENERAL ASSEMBLY
Forty-seventh session
Item 12 of the preliminary list*
REPORT OF THE ECONOMIC AND SOCIAL COUNCIL

ECONOMIC AND SOCIAL COUNCIL
Substantive session of 1992
Item 6 of the provisional agenda
COORDINATION QUESTIONS

Products harmful to health and the environment

Report of the Secretary-General

CONTENTS

		Paragraphs	Page
I.	INTRODUCTION	1 - 5	3
II.	REVIEW OF THE CONSOLIDATED LIST	6 - 33	4
	A. Arrangements for the production of the List	6 - 8	4
	B. Contents and scope of the List	9 - 19	5
	C. Format of the List	20	7
	D. Computer access	21	7
	E. Periodicity and language versions of the List	22 - 26	8
	F. Public health context	27	8
	G. Dissemination and utilization of the List	28 - 33	9

* A/47/50.

92-22372 3124c (E) 180692

250692

/...

CONTENTS (continued)

		Paragraphs	Page
III.	PENDING ISSUES AND FUTURE DIRECTIONS	34 - 48	10
	A. Prior informed consent	35 - 41	10
	B. Technical assistance	42 - 46	11
	C. Consumer products	47 - 48	13
IV.	CONCLUSIONS	49 - 50	13
Annex.	Criteria for the inclusion of pharmaceutical and chemical products in the Consolidated List		14

I. INTRODUCTION

1. The mandate for the production of the regular updates of the Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved by Governments 1/ dates back to 1982, with the adoption by the General Assembly of resolution 37/137 of 17 December 1982 on protection against products harmful to health and the environment. The Assembly requested the Secretary-General to base such a list upon the work already being done within the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO), the International Labour Organisation (ILO), the United Nations Environment Programme (UNEP), the General Agreement on Tariffs and Trade (GATT), the United Nations Centre on Transnational Corporations and other relevant intergovernmental organizations. The Assembly specified that the List should be easy to read and should contain both generic/chemical and brand names, as well as the names of all manufacturers and a short reference to the decisions taken by Governments that had led to the banning, withdrawal or severe restriction of the products. The Consolidated List was first issued in December 1983 and revised in July 1984. The information contained within the List was based on replies received from 60 Governments relating to nearly 500 products.

2. After considering the report of the Secretary-General (A/39/452), prepared in response to General Assembly resolution 38/149 of 19 December 1983, the Assembly, in paragraph 5 of its resolution 39/229 of 18 December 1984, decided, inter alia, that an updated Consolidated List should be issued annually and that the data should be made available to Governments and other users in such a form as to permit direct computer access to it. In order to keep costs to a minimum, the List was to be published in all the official languages of the United Nations on an alternating basis, with no more than three languages per year and with the same frequency for each language. The Assembly also decided that the format of the Consolidated List should be kept under continuing review, with a view to its improvement in cooperation with the relevant organs, organizations and bodies of the United Nations system, taking into account its complementary nature, the experiences obtained and the views expressed by Governments. The first triennial review was to be submitted to the Assembly at its forty-first session. After considering the first review (A/41/329-E/1986/83), the Assembly, in its decision 41/450 of 8 December 1986, endorsed Economic and Social Council resolution 1986/72 of 23 July 1986, whereby the Council decided that the List should continue to be published as one document, including generic/chemical and brand names and all manufacturers of such products.

3. The second triennial review was submitted to the General Assembly at its forty-fourth session (A/44/276-E/1989/78). The Assembly consequently adopted resolution 44/226 of 22 December 1989, which, in its second part, covered protection against products harmful to health and the environment. The Assembly noted with appreciation the cooperative relationship established between the United Nations, WHO and the UNEP International Register of Potentially Toxic Chemicals (IRPTC) in the preparation of the List. It also

noted the need to utilize the work being done by GATT with respect to the export of domestically prohibited goods and by UNEP and FAO in connection with the implementation of prior informed consent schemes for chemicals and pesticides in international trade.

4. The General Assembly also requested the Secretary-General to ensure the publication of the List in English, French and Spanish, in accordance with demand, while bearing in mind the need for it to be made available in all official languages. Finally, it requested him to consider ways and means of ensuring more effective involvement of non-governmental organizations in promoting a wider dissemination and utilization of the List.

5. Within the scope of the third triennial review, the Secretary-General was requested to make suggestions on ways and means of providing technical assistance, particularly to developing countries, to strengthen their capacity to utilize the List, and to study all pending issues, such as sustainable alternatives to banned and severely restricted products and unregistered pesticides.

II. REVIEW OF THE CONSOLIDATED LIST

A. Arrangements for the production of the List

6. The arrangements for the production of the Consolidated List have remained the same as reported in the first triennial review. It will be recalled that in 1985 the United Nations Secretariat, in close cooperation with WHO and UNEP/IRPTC, carried out a review of the List. The review covered arrangements for the preparation of future issues, the need for criteria for the inclusion of products, the question of introducing into the List certain types of information, such as the legal and public health context of regulatory actions, that had not been included in the first issue of the List, and the treatment of commercial data.

7. As a result, a memorandum of collaboration was agreed upon that outlined the division of responsibilities among the United Nations, WHO and UNEP/IRPTC, taking into account their respective competences and the concerns expressed by Member States. Accordingly, WHO collects, screens and processes the information relating to regulatory measures taken by Governments on pharmaceutical products and on the health-related and environmental reasons for these measures, and UNEP/IRPTC performs a similar function with regard to chemical products and consumer products that are regulated because of their chemical ingredients. The United Nations Secretariat coordinates these inputs, ensures that relevant information available in other organizations is utilized for the purposes of the List and collects and reviews the commercial data. It also edits, translates and publishes the List.

8. The previous report of the Secretary-General noted that collaboration among the organizations involved in the production of the List was working satisfactorily. Such arrangements continue at present. As at 1 March 1992,

however, the former Department of International Economic and Social Affairs and the Centre for Transnational Corporations ceased to operate as separate entities within the United Nations Secretariat. Their mandates have been subsumed under the new Department of Economic and Social Development. That Department now has the lead responsibility for the issuance of the regular updates of the Consolidated List, as well as for the commercial information currently contained in part II of the publication.

B. Contents and scope of the List

9. With each ensuing edition of the Consolidated List, there is an increase in the numbers of products and reporting Governments. The fourth issue, which was published at the end of 1991, covered regulatory actions taken by 92 Governments on over 600 products. It will be recalled that the second issue, which was the previous official publication, covered less than 600 products regulated by 67 Governments. The third issue was not published as an official document, for reasons described below.

10. With respect to the content of the List, it should be noted that decisions taken by a limited number of Governments on a specific product may not be representative of other Governments' positions, particularly in view of differing risk-benefit considerations. It is also important to realize that all pharmaceutical and chemical products are potentially harmful, if not correctly used. In addition, the fact that a given product is not listed as regulated by a country does not necessarily mean that it is permitted in that country; it may mean that the relevant regulatory decision has not been communicated to the United Nations, WHO or UNEP. Alternatively, in the case of pharmaceuticals and pesticides, which are frequently subject to compulsory registration procedures, the product may not have been submitted for registration.

11. The application of criteria for the inclusion of pharmaceutical and chemical products in the List (see annex) has significantly facilitated the screening of information to be contained in the publication. It is expected that the variance that continues to exist among Governments with respect to the criterion "severely restricted" will lessen through the implementation of the system of prior informed consent developed jointly by FAO and UNEP (see below).

12. The scope of information contained in the fourth issue remains the same as for previous issues. Part I, compiled by the United Nations, WHO and UNEP/IRPTC, covers both monocomponent and combination pharmaceutical products and chemical products. Psychotropic and narcotic substances have been included only in cases where a country has notified WHO either that the substance is controlled more rigorously than is provided for under the relevant international conventions or that the substance has been subjected to national control before being considered for international scheduling.

13. The information on chemical products continues to refer to products that have been banned for health or environmental reasons, or are only authorized for specified uses. The List does not cover the large number of widely used industrial chemicals to which occupational exposure limits, for example, maximum allowable concentrations, have been assigned by national authorities, on which information is available in ILO and IRPTC publications. Food additives, for which international standards have been established under the FAO/WHO Codex alimentarius, also continue to be outside the scope of the List. Information relating to consumer products has been limited to those products which are hazardous because of their chemical composition. The possible expansion of this section of the List is discussed below, under the chapter entitled "Pending issues and future directions".

14. With regard to agricultural and industrial chemicals, it should be noted that regulations often refer to chemical groups, such as arsenic compounds, rather than to specific chemicals. Starting with the third issue of the List, references to such more generally applicable regulations are made jointly with those of the chemical element representing the group - in the above case, arsenic. Similarly, information concerning salts, esters or other groups of derivatives is grouped with the acid or other main compound.

15. Products are listed alphabetically within sections. International non-proprietary names have been used whenever possible to identify pharmaceutical products and International Organization for Standardization (ISO) names, where available, have been used for chemicals. Each product entry includes, where available, the Chemical Abstracts Service registry number (CAS number), other scientific names, common names and synonyms; the effective date on which the regulation came into force; a summary of regulatory measures taken by Governments; brief explanatory comments where possible; and legal and bibliographical references. A listing of the references cited in part I and, if available, the addresses where copies of the documents can be obtained are given in an annex to the List.

16. Part II of the List, compiled by the United Nations Secretariat, presents commercial information, including data on trade names and manufacturers, relating to a large proportion of the products in part I. It provides an easy method to cross-reference commercial names with the recognized common scientific names. Trade-name data are included for most of the chemical products and monocomponent pharmaceutical products; there are no trade-name data for combination pharmaceuticals. Owing to limited resources, manufacturer data are provided only in respect of agricultural and industrial chemicals. For widely manufactured generic products, manufacturer data are not included. In this context, it should be noted that, since manufacturers and distributors may maintain a trade name while changing the ingredients or formulation, it is important to check the contents of a specific product using an identified trade name.

17. The commercial data were compiled through a review of various on-line databases and commercial directives for alternative nomenclature for the regulated products. Commercial names were then separated from alternate

scientific names. Data on individual manufacturers were gathered primarily from scientific and commercial publications and export marketing lists of various countries; they were collected irrespective of the manufacturer's form of ownership and include transnational and national enterprises from all regions. Manufacturer data relating to transnational corporations were verified in accordance with the procedure established with the Commission on Transnational Corporations. Other manufacturer data were checked against published sources. It is expected that these procedures will continue under the mandate of the Department of Economic and Social Development.

18. In recent years, special efforts have been made to obtain manufacturers' data with respect to state-owned chemical enterprises, through requests addressed to the permanent missions of Member States known to have state-owned chemical enterprises. Replies received in 1992 to date, which will be incorporated in the fifth issue, have come from 11 countries. For the previous issue, only one such reply had been obtained. The Secretary-General is pleased to note this development, which underscores a cooperative spirit on the part of Governments.

19. The commercial information is organized under the same headings as the regulatory data in order to facilitate easy reference. Each product entry includes the product name and CAS number, a listing of known trade names and, for certain products, a listing of known manufacturers, as an indication of where the manufacturers are based, and the trade names used by the manufacturers.

C. Format of the List

20. The General Assembly, in its resolution 37/137, agreed, inter alia, that the List should be "easy to read and understand". To this end, a new format and graphic presentation of the data were developed. The typeset of the fourth issue is larger, the characters are in upper and lower case, and a new cover has been designed. Aside from making the book more readable, the improved design is expected to increase sales revenue.

D. Computer access

21. The question of direct computer access, called for by the General Assembly in its resolution 39/229, is under study. Since the previous report of the Secretary-General, the information contained in the List has been downloaded from the mainframe to personal computers. It is expected that by the time this project is next reviewed, preparations for distributing the report on diskette will have been completed. In this connection, the Department of Economic and Social Development is studying the feasibility of including a user interface to allow for data queries, as well as of making the information available in a similar manner through modems.

E. Periodicity and language versions of the List

22. The General Assembly, in its resolutions 37/137 and 38/149, requested that the Consolidated List should be updated regularly, but did not specify the periodicity or languages. Therefore, the first issue and its revision were published, in 1983 and 1984 respectively, in English only. In its subsequent resolution 39/229, the Assembly stipulated that the List should be published and made available in all the official languages of the United Nations in sets of alternating languages each year, with no more than three languages per year and with the same frequency for each language. The revised first issue was translated into Arabic, French and Spanish and was published in 1986. The second issue of the List came out in English, Chinese and Russian.

23. As was noted in the second triennial review, the rationale behind the language rotation established pursuant to resolution 39/229 had been to keep costs to a minimum. However, given the sales demand for the List in English as well as the fact that the database is maintained and updated in that language, such a rationale was not well founded.

24. The General Assembly considered the argument put forward in the second triennial review that the sales figures for the List in English, which would not require translation, far surpassed that for other languages. Pursuant to resolution 44/226, the List is now scheduled to be published in English, French and Spanish, in accordance with demand, while bearing in mind the rotation established in resolution 39/229.

25. The fourth issue was published in English in December 1991 and distributed to member Governments by the Secretary-General under cover of a note verbale dated 2 March 1992. It is being translated into French and Spanish as the present report is being written and will be published as soon as available. It is anticipated that the fifth issue will be published in English in December 1992, with versions in Arabic, Chinese and Russian following in 1993.

26. The study of the periodicity and availability of the List in the official languages should continue in tandem with the question of direct computer access. Databases are being developed to allow for the continual updating of the List in all languages; however, the capacity currently exists only for English, French and Spanish.

F. Public health context

27. WHO regularly provides explanatory comments on pharmaceutical products to provide a context for certain regulatory actions. These comments serve to clarify cases in which Governments have taken conflicting regulatory actions in the light of different national priorities. UNEP/IRPTC and the International Programme on Chemical Safety, a joint programme of ILO, UNEP and WHO, are not in a position to provide comments on regulatory actions related

to agricultural and industrial chemicals, owing to the sheer number of products in which these chemicals appear and the manifold applications of such products. Moreover, it is virtually impossible to comment on prohibitions or use restrictions for chemical products as risk-benefit assessments and subsequent decisions may differ considerably from country to country depending on different national or local conditions most frequently incompletely known to IRPTC and the International Programme on Chemical Safety.

G. Dissemination and utilization of the List

28. In order to determine the use to which the List is being put, a questionnaire has been included in each issue, starting with the second issue. As the present report is being written, it is too early to provide feedback on the use of the fourth issue. That information will be made available to the General Assembly in the context of its consideration of the present report.

29. Certain observations can be made with respect to the utilization and dissemination of the List since its inception. The List is unique in being the only document that presents, in a unified manner, information on restrictive regulatory decisions taken by Governments on a range of pharmaceutical products and agricultural and industrial chemicals. As such, it is a valuable source of information for Governments in considering the scope for eventual regulatory actions.

30. The General Assembly requested the Secretary-General to consider ways and means of ensuring more effective involvement of non-governmental organizations in promoting the dissemination and utilization of the Consolidated List. The Department of Economic and Social Development regularly receives requests for copies of the List from non-governmental organizations. The fourth issue is being sent to such groups as the Pesticide Action Network, which links over 300 groups in 50 countries. The Executive Director of the Network for Asia, in a recent letter to the Department, wrote:

> "We have found the Consolidated List an important tool in our work to curb the overuse and misuse of pesticides and in promoting alternatives to pesticides ... Information about the List will be disseminated to more than 200 groups in the region and elsewhere. We will also review it in our newsletter, The Pesticide Monitor."

31. Other organizations, such as the International Organization of Consumers Unions, a world-wide organization of 174 national, quasi-governmental, regional, umbrella and independent consumer groups in 67 countries, uses the information contained in the List in its project Consumer Interpol. It monitors the use of hazardous products through its national constituents and distributes information to policy makers, the media and consumers with the aim of removing such products from the market. The Director-General of the International Organization of Consumers Unions recently wrote to the Secretary-General to thank him for his efforts in publishing the List.

32. Greenpeace, a non-governmental organization with 30 offices around the world, wrote to the Department that the List is "an invaluable reference source". Copies have been sent to all its offices for information dissemination among its members.

33. Departmental copies are also sent to grassroots consumer groups in developing countries. To this end, the Department maintains a computerized mailing database, which is regularly updated.

III. PENDING ISSUES AND FUTURE DIRECTIONS

34. An important element in keeping the Consolidated List under continuous review is to make it more useful and relevant to national authorities charged with the responsibility of making informed decisions on the availability of chemicals and pharmaceuticals in their respective countries. Efforts will continue to be made to improve its format, expand its coverage and add new information so as to ensure that it continues to serve its intended purpose of providing consolidated information on hazardous products based upon the work of the organizations of the United Nations system and other concerned intergovernmental organizations. In recent years, there have been a number of developments that will have an impact upon the future direction of the List.

A. Prior informed consent

35. The General Assembly, in its resolution 37/137, agreed that products that have been banned from domestic consumption and/or sale because they have been judged to endanger health and the environment should be sold abroad by companies, corporations or individuals only when a request for such products is received from an importing country or when the consumption of such products is officially permitted in the importing country. In its resolutions 38/149 and 39/229, the Assembly requested the organizations of the United Nations system to provide the necessary technical assistance to the developing countries, at their request, for the establishment or strengthening of national systems for managing hazardous products, as well as for an adequate monitoring of the importation of those products. In its resolution 42/186 of 11 December 1987, the Assembly also recommended that trade in hazardous industrial products, such as toxic chemicals and pesticides, and in some other products, such as pharmaceuticals, should be subjected to regulations to ensure sharing by the contracting parties, Governments and consumers of information on their environmental and health implications and on methods for their safe use and disposal.

36. In its resolution 44/226, the General Assembly noted the need to assist all countries, particularly developing countries, in obtaining all appropriate information concerning toxic and dangerous products and wastes, and in reinforcing their capacity to detect and halt any illegal attempt to introduce toxic and dangerous products and wastes to other States, as well as traffic not carried out in compliance with internationally accepted guidelines and principles in the field.

37. Both UNEP and FAO have elaborated guidelines for the principle of prior informed consent, whereby the international shipment of a chemical that is banned or severely restricted, in order to protect human health or the environment, should not proceed without the explicit agreement of the designated national authority in the importing country having been provided with all the relevant information.

38. In the case of FAO, a government consultation was held at Rome, from 10 to 15 January 1989, to propose, inter alia, amendments to the International Code of Conduct on the Distribution and Use of Pesticides, which had come into force in 1985. It was suggested that prior informed content, in the context of the Code, would mean that the international shipment of a pesticide that is banned or severely restricted, in order to protect human health or the environment, should not proceed without the explicit agreement of the designated national authority in the importing country having been provided with all the relevant information.

39. FAO and UNEP are sharing the operational responsibility for the implementation of the prior informed consent procedure, whereby the decisions of importing countries as to whether they wish to receive future shipments of chemicals that have been banned or severely restricted are formally obtained and disseminated. The two organizations jointly manage common elements, including the selection of chemicals, the preparation of decision guidance documents, mechanisms for information sharing and the creation of databases.

40. All designated national authorities have been asked to prepare an inventory of all control actions to ban or severely restrict chemicals in their countries. In addition to the chemicals identified through the notification system under the procedure, FAO and UNEP have provided for the possibility of including acutely hazardous pesticides that are not necessarily banned or severely restricted in any country, but are known to be causing health or environmental problems, particularly in developing countries. To this end, FAO and UNEP have sent out a questionnaire to designated national authorities. Once responses are received, the FAO/UNEP Joint Group of Experts on Prior Informed Consent will take a decision on whether or not to include any of these pesticides in the prior informed consent procedures.

41. The operation of these procedures has begun and will be reflected in the content of the fifth issue of the List. Those chemicals subject to prior informed consent and those countries participating in the process will be identified. The possibility of including additional information for those chemicals, such as alternatives, is being investigated, pursuant to General Assembly resolution 44/226.

B. Technical assistance

42. Both FAO and UNEP have a number of activities under way to train national officials in the operation of the prior informed consent procedure and to strengthen the decision-making and regulatory capability of developing

countries. FAO has held regional workshops in Thailand, the Philippines, New Caledonia, Chile and Ghana which included modules and case-studies on prior informed consent. Two subregional workshops on pesticide management were held in Africa and regional workshops were convened during the last two years in Latin America and the Caribbean. Individual national workshops on the control and safe and effective use of pesticides were also held.

43. FAO is operating a project on the implementation of the International Code of Conduct on the Distribution and Use of Pesticides in Asia and the Pacific, under a trust fund financed by the Government of Japan. Under this project a joint FAO/UNEP workshop on the implementation of prior informed consent was recently held in the Philippines. In addition, FAO will be implementing projects in Central America with the support of the Government of the Netherlands, in the Caribbean and parts of South America with support from the Government of Japan, while a project for Africa has been approved by UNDP. These projects are aimed at assisting Governments in implementing the provisions of the Code of Conduct, of which prior informed consent is an integral part.

44. UNEP/IRPTC has organized and supported several training activities related to the implementation of the London Guidelines for the Exchange of Information on Chemicals and International Trade, and of prior informed consent. Those activities included a national workshop on the implementation of the London Guidelines in Malaysia in February 1990 and a regional workshop for Eastern European countries in Moscow in December 1990. Another national workshop was held in Beijing in October 1991.

45. UNEP/IRPTC has recently established a training programme together with the United Nations Institute for Training and Research (UNITAR) on the implementation of the London Guidelines and the establishment of national registers of potentially toxic chemicals in developing countries. Training activities started in the Asia and Pacific region with the FAO/UNEP workshop at Manila in August. A subregional joint IRPTC/UNITAR follow-up workshop was held at Kuala Lumpur in December 1991. This workshop brought together senior administrative and legal professionals from various sectors of government who are involved in the implementation of prior informed consent at the national level. The training programme will gradually be extended to the Latin American and African regions as experience is gained. The experience of the first series of workshops will allow IRPTC and UNITAR to develop training material on various aspects of the prior informed consent procedure. Prior informed consent training modules will be developed in close cooperation with FAO.

46. At its 16th session, in May 1991, the UNEP Governing Council recommended that UNEP continue developing model national legislation to assist in the implementation of the amended London Guidelines, in close consultation with Governments and relevant international and intergovernmental organizations. Work is now under way to develop such legislation further.

C. Consumer products

47. At present, information relating to consumer products in the List has been limited to those products which are hazardous because of their chemical composition. In its resolution 44/226, the General Assembly noted the need to utilize the work being done by the GATT Working Group on the Export of Domestically Prohibited Goods and Other Hazardous Substances. That Group, which was established in 1989, is considering the establishment of a notification system for products that are banned or severely restricted domestically but are still exported. The system would cover those products not already covered under other international agreements. As the present report is being written, a decision of the Group is still pending.

48. The present report is being finalized prior to the convening of the United Nations Conference on Environment and Development at Rio de Janeiro in June 1992. It should be noted in this context that the Consolidated List will continue to be an important tool for the dissemination of information on products harmful to health and the environment and, as such, a means to facilitate the environmentally sound management of toxic chemicals, an issue that is an important aspect of Agenda 21, the main working document of the Conference.

IV. CONCLUSIONS

49. Many activities are being undertaken by the United Nations system to help developing countries protect themselves from hazardous products. It is beyond the scope of the present report to document all these efforts, the most notable among them being the convening of the United Nations Conference on Environment and Development in June 1992. In tandem with such work, the international community has taken increased notice of the need to safeguard present and future generations against the noxious effects on human health and the environment of hazardous products.

50. The Consolidated List should continue to refer to all the relevant work being accomplished within the system and ensure that for each product entry reference is made to the relevant complementary publications and international conventions.

Notes

1/ For the first and second issues of the Consolidated List, see United Nations publications, Sales Nos. E.85.IV.8 and E.87.IV.1.

ANNEX

Criteria for the inclusion of pharmaceutical and chemical products in the Consolidated List

1. Pharmaceutical products a/

(a) "Banned product"

A product that has been withdrawn from use and/or sale nationally in one or more countries by order of the competent national authority, having regard to its safety in relation to its intended use.

(b) "Voluntary product"

A product that has been withdrawn from use and/or sale nationally in one or more countries by voluntary action of the manufacturer, having regard to its safety in relation to its intended use.

(c) "Severely restricted"

A product containing:

(i) A substance that is controlled more rigorously than is provided for under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances or that is subjected to analogous control at the national level before it has been considered for international scheduling;

(ii) A substance that may be incorporated in pharmaceutical dosage forms only within the specific limits determined by statute;

(iii) A substance that is approved by a competent national authority and is subsequently subjected to restrictions that exclude its use in a substantial proportion of the potential target population of patients having regard to its safety. A substance that from the outset has been severely restricted in its indications having regard to the known balance of safety and efficacy is excluded.

(d) "Non-approved"

A product that has been formally submitted for registration by a manufacturer to a national competent authority and which has been rejected on grounds of safety.

2. Chemical products

(a) "Banned"

A product that has been prohibited for all uses nationally in one or more countries by final government regulatory action because of health or environmental reasons.

(b) "Withdrawn"

A product formerly in commerce that has been withdrawn for all uses nationally in one or more countries by final voluntary action of the manufacturer because of health or environmental reasons.

(c) "Severely restricted"

A product for which virtually all uses have been prohibited nationally in one or more countries by final government regulatory action because of health or environmental reasons, but for which certain specific uses remain authorized.

Notes

a/ Products that are in illicit trade only would not be considered.